

REMARKS

Claims 1, 3-5, 10, 11, 15, 25 and 29-33 are pending in this application. By this Amendment, claim 2 is canceled; claims 1, 3, 4, 11, 15 and 29 are amended; and claims 30-33 are added herein.

Starting on August 18, 2005, Applicants' undersigned representative began contacting the Examiner in an effort to schedule a personal interview before filing a response to the outstanding Office Action. The Examiner indicated that she was not available for a personal interview until October. Thus, it was agreed that a response to the Office Action would be filed to avoid further extensions of time and that the Examiner would grant a personal interview before acting on the response as filed. A Request for Interview is therefore attached hereto.

Claims 1-5 and 10 are rejected under 35 USC §102 over Schoedon et al. Applicants respectfully traverse the rejection.

Schoedon reports a study carried out on cultures of bacteria reported as *Tropheryma whippelii* in human blood monocytes. However, as discussed in depth in the attached Declaration, Schoedon does not teach a culture according to claim 1. In particular, Schoedon does not teach a culture in which the *Tropheryma whippelii* bacterium is isolated and established in culture such that the bacterium reproducibly multiplies over time. As indicated in the Declaration, for one of ordinary skill in the art, it is implicit in the phrases "established in culture" and "multiplies over time" that the ratio of bacteria to cells increases. In addition, it is also implicit in these phrases that the culture can be maintained over time, i.e., indefinitely. However, because of the life cycle of human monocyte cells and the doubling time of *Tropheryma whippelii* bacteria, these features would not be obtained in the culture described in Schoedon. See paragraph 10 of the attached Declaration. In addition, as described in the attached Declaration, Schoedon does not teach a culture according to claim 1 in a way that it can be reproduced. *See In re LeGrice*, 301 F.2d 929, 133 USPQ 365 (CCPA

1962) (when claims are drawn to plants, the reference, combined with knowledge in the prior art, must enable one of ordinary skill in the art to reproduce the plant).

Claim 4 is directed to an antigen isolated from the *Tropheryma whippelii* bacterium obtained from a culture according to claim 1. In rejecting this claim, the Office Action indicates that "[s]ince isolated bacteria is routinely used as an antigen in the art, the bacteria isolated from PMNC read on claims 3-5 and 10." However, claim 4 clearly does not read on an entire bacterium. Instead, claim 4 clearly recites an antigen that is isolated from a bacterium. Schoedon clearly fails to teach such an antigen in isolated form.

Schoedon does not teach each and every feature of claims 1 and 4. Therefore, the rejection over Schoedon of claims 1 and 4, as well as claims 3, 5 and 10, which depend from claims 1 or 4 should be reconsidered and withdrawn.

Claims 1-5 and 10 are rejected under 35 USC §102 over Muller et al. Applicants respectfully traverse the rejection.

As with Schoedon, Muller reports a study carried out on cultures of bacteria they reported as *Tropheryma whippelii* in human blood monocytes. However, for the same reasons discussed above with regard to Schoedon, Muller does not teach a culture comprising a *Tropheryma whippelii* bacterium isolated and established in culture such that the bacterium reproducibly multiplies over time. In addition, Muller does not teach or suggest an antigen isolated from a bacteria obtained from such a culture. Therefore, Muller does not teach each and every feature of claims 1-5 and 10. Thus, the rejection over Muller should be reconsidered and withdrawn.

Claims 1-5 and 10 are rejected under 35 USC §102 over Drancourt. Applicants respectfully traverse the rejection.

As discussed in the attached Declaration of Professor Drancourt, the author of the applied Drancourt reference, this reference merely provides a summary of various articles concerning *Tropheryma whippelii*. It does not set forth the results of further experimentation.

In particular, Drancourt does not reflect any experimentation that was conducted to confirm the accuracy or repeatability of the work described in Schoedon. Instead, this paper merely summarized the work of researchers in the field such as reported in the scientific literature, including Schoedon. See paragraph 12 of the attached Declaration. Thus, Drancourt fails to teach the present claims for at least the same reasons as Schoedon. Therefore, the rejection over Drancourt should be reconsidered and withdrawn.

Claims 11, 15, 25 and 29 are rejected under 35 USC §103 over Schoedon or Muller or Drancourt in view of Harlow and Lane. Applicants respectfully traverse the rejections.

None of Schoedon, Muller or Drancourt teach the claimed diagnostic tests. In addition, Harlow and Lane is merely a laboratory manual that generally describes types of immunoassays. Harlow and Lane does not teach or suggest using *Tropheryma whippelii* bacteria or an antigen obtained therefrom in an immunoassay to diagnose diseases associated with *Tropheryma whippelii* infection.

In addition, as described in paragraph 11 of the attached Declaration, it is practically and biologically impossible to establish in culture *Tropheryma whippelii* for diagnostic purposes in IL4 deactivated human monocytes, as reported by Schoedon and Muller, because the mean lifetime of monocytes is only 30 days, and monocytes cannot be furnished in sufficient amount to establish a bacterium in culture for biological diagnostic purposes. Therefore, even assuming that any of Schoedon, Muller or Drancourt provides motivation to use a *Tropheryma whippelii* bacterium in diagnostic tests, these references do not teach or suggest the bacterium or an antigen thereof in a form in which the bacterium or antigen could be used in this way.

The cited references do not teach or suggest the methods of claims 11, 15, 25 and 29. Therefore, the §103 rejection should be reconsidered and withdrawn.

Claims 3 and 10 are indicated to be objected for depending on a rejected base claim. Thus, it appears that the Examiner did not intend to include claims 3 and 10 in the §102

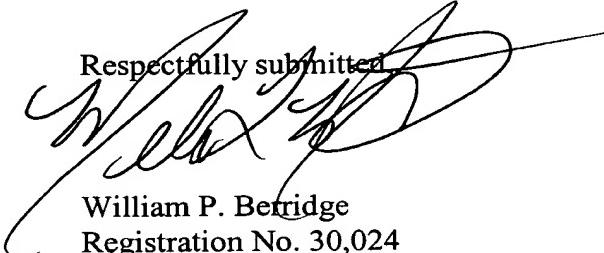
rejections. The Examiner is respectfully requested to clarify this in responding to this Amendment.

Claim 2 is also objected to based on the abbreviation "MEM." Claim 2 has been canceled herein rendering the objection to this claim moot.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 3-5, 10, 11, 15, 25 and 29-33 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,


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WPB:MLM/jam

Attachments:

132 Declaration
Request for Interview

Date: September 9, 2005

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